

HEALTH AND SENIOR SERVICES

SENIOR SERVICES AND HEALTH SYSTEMS BRANCH

HEALTH FACILITIES EVALUATION AND LICENSING DIVISION

OFFICE OF CERTIFICATE OF NEED AND HEALTHCARE FACILITY LICENSURE

Proposed Readoption with Amendments: N.J.A.C. 8:43D

Proposed New Rules: N.J.A.C. 8:43D Appendices A and B

Standards for Licensure of Pediatric Community Transitional Homes

Authorized By: Heather Howard, Commissioner, Department of Health and Senior Services (with the approval of the Health Care Administration Board).

Authority: N.J.S.A. 26:2H-1 et seq., specifically 26:2H-5.

Calendar Reference: See Summary below for explanation of exception to calendar requirement.

Proposal Number: PRN 2009-19.

Written comments on the proposal must be postmarked on or before March 6, 2009 and mailed to:

Ruth Charbonneau, Director
Office of Legal and Regulatory Affairs
Office of the Commissioner
Department of Health and Senior Services
PO Box 360
Trenton, NJ 08625-0360

The agency proposal follows:

Summary

The Department of Health and Senior Services (Department) proposes the readoption of N.J.A.C. 8:43D, Standards for Licensure of Pediatric Community Transitional Homes and also proposes amendments and new rules. N.J.A.C. 8:43D is scheduled to expire on December 1, 2008, in accordance with N.J.S.A. 52:14B-5.1 and Executive Order No. 66 (1978). In accordance with N.J.S.A. 52:14B-5.1c, the filing of this notice of proposal with the Office of Administrative Law prior to December 1, 2008, operates to extend the expiration date of N.J.A.C. 8:43D to May 30, 2009.

N.J.A.C. 8:43D, Standards for Licensure of Pediatric Community Transitional Homes, first became effective December 1, 2003, upon its adoption by the Department as new rules, with the approval of the Health Care Administration Board (HCAB). (35 N.J.R. 1016(a), 5400(a)). The Department has reviewed N.J.A.C. 8:43D and has determined that the existing rules continue to be necessary, adequate, reasonable, efficient, understandable and responsive to the purposes for which they were originally promulgated. Therefore, the Department proposes to readopt the chapter. The rules proposed for readoption would continue to provide the regulatory framework to fulfill the Department's obligation to assure access to pediatric community transitional homes of the highest quality.

The purpose of the rules proposed for readoption and the proposed amendments and new rules is to establish uniform licensing requirements for all pediatric community transitional homes in the State, which are intended to promote a coordinated array of supportive health care, personal and social services for medically fragile children. The Department expects that the rules proposed for readoption with amendments and new rules would provide uniformity and consistency in the delivery of pediatric community transitional home care Statewide. N.J.A.C. 8:43D is intended to ensure the quality of services provided by pediatric community transitional homes. The rules proposed for readoption are the product of collaboration between the Department and the Pediatric Community Transitional Home Licensing Standards Advisory Committee that commenced work on the rules in June, 1998, that are now proposed for readoption with amendments and proposed new rules. The Committee included representatives from all five of the State's existing pediatric community transitional homes. Additionally, staff from various State agencies, such as the Department of Children and Families, Department of Community Affairs and the Department's Office of Certificate of Need and Healthcare Facility Licensure, as well as its Division of HIV and AIDS Services, served as committee participants and technical advisors.

Following is a summary of the proposed amendments and new rules:

The Department proposes to amend N.J.A.C. 8:43D-1.3 to add definitions of the Department's licensing unit, "Office of Certificate of Need and Healthcare Facility Licensure" and health care facility inspection unit, "Office of Health Facilities Assessment

and Survey." The definitions reflect a Department reorganization of the administrative assignment of these units and would provide the units' respective addresses and telephone numbers. The Department proposes corresponding amendments throughout the chapter to delete references to the prior unit names and contact information, and to add references to the correct unit names. The Department proposes amendments to prior unit names and contact information in the following sections: N.J.A.C. 8:43D-2.1(a) and (d), 2.3(a) and (a)2, 2.4(a)9 and (b), 2.5, 2.6(b), 4.2(a), 4.3, 4.7(a) and 14.3(b)7. The Department also proposes an amendment at N.J.A.C. 8:43D-1.3 to the term "Commissioner" to add his or her designee.

The Department proposes to amend N.J.A.C. 8:43D-1.3 to add definitions of "Application for New or Amended Acute Care Facility License (CN-7)" and "Application for Waiver (CN-28)," which are the forms required to obtain a license and apply for a waiver, respectively. The proposed definitions would also set forth the method by which the forms may be obtained. Both of the forms are set forth in the proposed new rules at N.J.A.C. 8:43D Appendices A and B, respectively. Pediatric community transitional homes currently use the forms set forth in chapter Appendices A and B; they are not new requirements, however, the Department adds the forms in this rulemaking to provide better guidance for the regulated community. Consequently, the Department also proposes an amendment at N.J.A.C. 8:43D-2.1(a) to remove existing language regarding licensure forms and instead use the defined term "Application for New or Amended Acute Care Facility License (CN-7)" and explain the process for annual licensure renewal. Similarly, the Department proposes an amendment at N.J.A.C. 8:43D-2.6(b) and (c) to remove existing text about applying for a waiver and instead use the defined term "Application for Waiver (CN-28)" and remove duplicative language explaining waiver requirements.

N.J.A.C. 8:43D-4.7 is amended to specify that a facility shall notify the Department within three hours of reportable events.

The Department proposes an amendment at N.J.A.C. 8:43D-6.1(a)6 to delete reference to "control" of smoking in a facility and to replace it with reference to "prohibition" of smoking, and to delete the procedures for that "control" at N.J.A.C. 8:43D-6.1(a)6i through iv. The New Jersey Smoke-Free Air Act (Act), N.J.S.A. 26:3D-55 et seq., particularly at N.J.S.A. 26:3D-58, prohibits smoking in "indoor public places" and

"workplaces," and requires the owner or operator of a location subject to the Act to require compliance therewith. A pediatric community transitional home is both an "indoor public place" and a "workplace," as N.J.S.A. 26:3D-57 defines those terms ("Indoor public place' means a . . . health care facility licensed pursuant to [N.J.S.A.] 26:2H-1 et seq."; "'Workplace' means a structurally enclosed location or portion thereof at which a person performs any type of service or labor"). Thus, it would be inappropriate for the rule to continue to suggest that smoking, albeit "controlled" smoking, is appropriate in a pediatric community transitional home.

The Department proposes an amendment at N.J.A.C. 8:43D-15.2(c) in order to provide the current recommendation for immunizations, which is the 2008 Recommended Childhood and Adolescent Immunization Schedules approved by the Advisory Committee on Immunization Practices (ACIP), the American Academy of Pediatrics (AAP), and the American Academy of Family Physicians (AAFP), which is amended yearly. The proposed amendment would also set forth how to obtain the recommended immunization schedule. The Department also proposes an amendment at N.J.A.C. 8:43D-15.2(c)1 to provide a cross-reference to N.J.A.C. 8:57-4, which sets forth the immunization requirements for entry into and attendance in schools, preschools and child-care centers in New Jersey. ACIP has recommended the use of the vaccines currently mandated by N.J.A.C. 8:57-4. The AAP, AAFP and the Public Health Council also endorses the use of these vaccines. The Department follows the periodically revised recommendations of the ACIP for the routine administration of each communicable disease vaccine to the pediatric population, as applicable to New Jersey.

The Department also proposes to amend N.J.A.C. 8:43D-15.4(a) and (b). The Department proposes to amend the rule to incorporate the most recent publication of "Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health Care Settings, 2005," MMWR. December 30, 2005, volume 54, Number RR-17, p. 1-141, pursuant to the Occupational Safety and Health Act (OSH ACT) of 1970. The Department proposes an amendment at N.J.A.C. 8:43D-15.4(a)1 to provide an option for how to test for tuberculosis by adding interferon gamma release assay (IGRA) as an acceptable test and to establish the meaning of a positive, negative or intermediate test result. The Department proposes amendments throughout N.J.A.C. 8:43D-15.4(a) to add IGRA as an

optional test for tuberculosis. The Department proposes an amendment at recodified N.J.A.C. 8:43D-15.4(a)1ii and iii to establish when a second test or medical evaluation is necessary to determine latent or active tuberculosis disease. The Department proposes new N.J.A.C. 8:43D-15.4(a)3i(1) and (2) to establish when medical evaluation is required and also the requirements for returning to work for an asymptomatic employee and a symptomatic employee. The Department proposes an amendment at existing N.J.A.C. 8:43D-15.4(a)3ii(2) to remove the requirement for submitting Mantoux tuberculin testing results for employees to the Department. The Department proposes an amendment at N.J.A.C. 8:43D-15.4(m) to remove the word contagious and instead use the defined term communicable and also to provide a cross-reference for required reporting to N.J.A.C. 8:57-2 and 5, which contain reporting requirements that are applicable to pediatric community transitional homes.

Following is a summary of the rules proposed for readoption:

N.J.A.C. 8:43D-1

The rules proposed for readoption at Subchapter 1 would continue to state the purpose and scope of the rules, stipulating that all pediatric community transitional homes would be required to comply with the rules for minimum standards set forth in the chapter in order to be licensed to operate in New Jersey. The rules proposed for readoption at Subchapter 1 would continue to define the words and terms used throughout the chapter.

N.J.A.C. 8:43D-2

The rules proposed for readoption at Subchapter 2 would continue to establish licensure procedures. N.J.A.C. 8:43D-2.1 would continue to outline the procedure for obtaining a license, which includes the information needed for completing a license application, application filing, renewal and inspection fees, State track record requirements and a provision exempting pediatric transitional care homes from the requirement for a certificate of need. N.J.A.C. 8:43D-2.2 would continue to establish procedures for plan reviews for newly constructed, renovated and expanding facilities. N.J.A.C. 8:43D-2.3 and 2.4 would continue to set forth the survey process and the requirements for the issuance of a license, posting of the license, transfer of ownership process, annual renewal and penalties for noncompliance. N.J.A.C. 8:43D-2.5 would continue to require 30-days' notice to the Department prior to surrendering a license. N.J.A.C. 8:43D-2.6 and 2.7 would

continue to set forth the waiver application filing procedure and articulate the Commissioner's authority to take licensure enforcement action against facilities operating with licensure deficiencies. N.J.A.C. 8:43D-2.8 and 2.9 would set forth licensure applicant hearing rights and establish that only licensed pediatric community transitional homes may describe or offer themselves to the public as providing these services.

N.J.A.C. 8:43D-3

Subchapter 3 would continue to establish standards for new buildings, alterations, renovations and additions to existing buildings for pediatric community transitional homes in accordance with the New Jersey Uniform Construction Code. Specifically, N.J.A.C. 8:43D-3 would continue to articulate requirements for ventilation; exit access passageways and corridors; installation and location of automatic fire detection systems; the provision of fire suppression systems; and interior wall, ceiling and floor finish. (N.J.A.C. 8:43D-3.2 through 3.6) N.J.A.C. 8:43D-3 would continue to establish the square footage requirements for residential units; the availability of toilets, baths and handwashing sinks for residents, staff and visitors; community space (square footage) for each resident; and the physical plant requirements for laundry equipment. (N.J.A.C. 8:43D-3.7 through 3.10) N.J.A.C. 8:43D-3 would continue to set forth the minimum food service facilities requirements; space requirements for administrative functions and public areas where private visits and interviews may take place; the number of fire extinguishers and their specifications; and the use of sounding devices. (N.J.A.C. 8:43D-3.11 through 3.14).

N.J.A.C. 8:43D-4

N.J.A.C. 8:43D-4.1 would continue to establish the minimum services to be provided to residents, such as: assistance with personal care, nursing, pharmacy, dining, activities, recreational and social work services and other services necessary to meet the individual needs of each resident. N.J.A.C. 8:43D-4.1 would continue to set forth the criteria for both the administration of and self-administration of over-the-counter medications and provisions for age-specific resident education when required. N.J.A.C. 8:43D-4.2 would continue to establish reporting requirements for ownership and change of ownership and the prohibition of person(s) convicted of a crime relating to their capability of owning or operating a facility from having ownership interest in the facility. N.J.A.C. 8:43D-4.2(c) would continue to provide waiver provisions for prospective owners or

operators of pediatric transitional homes, convicted of a crime cited in N.J.A.C. 8:43D-4.2(b), who have either been rehabilitated or had their conviction expunged. N.J.A.C. 8:43D-4 would continue to establish requirements for document reporting; a policy and procedure manual to oversee the operation of the facility; and written provisions to ensure resident transportation for essential services. (N.J.A.C. 8:43D-4.3 through 4.5) N.J.A.C. 8:43D-4.6 would continue to require the establishment of written agreements for services not provided directly by the facility and N.J.A.C. 8:43D-4.7 would continue to establish those sets of circumstances that must be immediately reported to the Department and confirmed in writing within 72 hours, among which, are disease epidemics, fires, disasters, power outages, crimes against the residents and suspected patient abuse. N.J.A.C. 8:43D-4.7 would continue to include a notification requirement that the resident's family, guardian and/or designated responsible person or community agency be notified in addition to the Department upon the occurrence of certain enumerated events, such as serious accidents, criminal acts, resident transfer and resident death.

N.J.A.C. 8:43D-4.8 would continue to establish a public posting requirement to inform interested parties on how to obtain available information pertaining to licensure waivers, the last annual licensure inspection, policies for resident rights, security procedures, telephone numbers for reporting abuse and a mechanism by which to contact the facility's governing body during regular business hours. N.J.A.C. 8:43D-4.9 would continue to articulate the requirement for maintaining records with respect to annual admissions and discharges, as well as statistical data regarding resident census and facility characteristics. N.J.A.C. 8:43D-4.10 and 4.11 would continue to set forth requirements for admitting residents to a pediatric community transitional home, which include a provision for the admission of residents regardless of their ability to pay and an involuntary discharge process, including an appeal process.

N.J.A.C. 8:43D-5

N.J.A.C. 8:43D-5.1 would continue to establish the requirement to appoint an administrator and provide a written designation of an alternate. N.J.A.C. 8:43D-5.2 would continue to require an administrator of a pediatric community transitional home to be an individual who is at least 21 years of age and has a bachelor's degree with two years of experience in management or supervision or six years of experience in a health care or

human services related position, of which two shall be in management or supervision. N.J.A.C. 8:43D-5.3 would continue to articulate the responsibilities of the administrator, including, but not limited to, ensuring the development, implementation and enforcement of all policies and procedures to operate the facility and establishing a liaison and communication role with facility staff, residents, residents' families, hospitals and mental health agencies. N.J.A.C. 8:43D-5.4 through 5.10 would establish the qualifications for dietitians or dietitian consultants, licensed practical nurses, child care workers, pharmacists or pharmacist consultants, primary care providers and social workers working at or for the pediatric community transitional home.

N.J.A.C. 8:43D-5.11 would continue to set forth the minimum staffing requirements, which establish the ratio of one child care worker for every three residents, with the provision that the facility, based on their needs assessment, would employ staff in sufficient numbers to provide basic care, assistance and supervision necessary for each resident. This section of the rules would continue to stipulate that the facility develop and implement a staff orientation, education and training plan, which includes at least annual in-service education addressing the following: interdisciplinary plans; emergency plans; infection control; and quality assurance. This section of the rules would continue to establish a staff scheduling and time verification policy, termination policy and infection control policy for reportable communicable disease for all personnel, including staff under contract.

N.J.A.C. 8:43D-5.12 would continue to set forth minimum staff requirements for pediatric residential care, which stipulates the licensing and experience qualifications for a full-time nursing director. N.J.A.C. 8:43D-5.12 would continue to set forth that one registered professional nurse be on duty for 40 hours per week and the same be available by telephone at all times. N.J.A.C. 8:43D-5.12 would continue to require the facility to establish staff monitoring and supervision policies to oversee the health, safety and general welfare of the residents on a 24-hour basis.

N.J.A.C. 8:43D-5.13 would continue to require each facility to retain a medical director licensed to practice medicine in New Jersey as a pediatrician or family practice physician with at least one year of experience providing medical care to children who will oversee the residents' care and medical care policies of the facility. N.J.A.C. 8:43D-5.13

would continue to establish the responsibilities of the medical director. N.J.A.C. 8:43D-5.13 would continue to require that primary care provider's orders be entered in each medical record, the medical director review resident medical records, as well as all reports of documented incidents and a primary care provider visit each resident at least every 30 days unless explicit justification for not doing so is entered into the medical record.

N.J.A.C. 8:43D-6

N.J.A.C. 8:43D-6 would continue to set forth the requirement of written resident care policies and procedures among which are resident rights, staffing levels, emergency medical and dental care, health education, smoking policies and resident discharge, termination, transfer and readmission. N.J.A.C. 8:43D-6 would continue to require the facility to develop written policies and procedures for monitoring the quality of health care services provided to residents, which would include: length of stay, medication errors, resident injury and resident mortality. N.J.A.C. 8:43D-6 would continue to establish the financial and payment arrangements pertaining to residents, which include maintenance of written financial records, informing the resident's legal guardian or appropriate party of changes in cost apart from those previously agreed upon through written notice and providing the party responsible for the resident with information regarding financial assistance.

N.J.A.C. 8:43D-7

N.J.A.C. 8:43D-7.1 would continue to set forth the requirement for resident assessment and care plans that stipulate completion of an assessment by a registered nurse. N.J.A.C. 8:43D-7.2 would continue to establish the policies and procedures for resident assessment and interdisciplinary care plans including, examination by a primary care provider within five days before or 48 hours after admission, completion of a comprehensive assessment of the resident within 10 days of admission to formulate the interdisciplinary care plan, and at least a quarterly update of the interdisciplinary care plan. N.J.A.C. 8:43D-7.3 would continue to require the facility to ensure the implementation of the interdisciplinary plan for each resident. N.J.A.C. 8:43D-7.3 would further continue to articulate the resident's family or responsible person's right to select their own physician.

N.J.A.C. 8:43D-8

Subchapter 8 would continue to establish standards governing dining services. N.J.A.C. 8:43D-8.1 would continue to require the facility to provide dining services to meet the daily nutritional needs of residents, including an initial dietary consultation and a follow-up nutritional consultation at least quarterly, or as needed. N.J.A.C. 8:43D-8.2 would continue to set forth the responsibilities of the dietitian or dietitian consultant, among which are nutritional assessment, implementation of the interdisciplinary plan, record maintenance, counseling services and education. N.J.A.C. 8:43D-8.3 would continue to set forth the requirements of dining services among which are an annual in-service training seminar provided by a dietitian or dietitian consultant, posting of a current menu, planned menus at least 14 days in advance, available between-meal snacks, adherence to the diet portion of the interdisciplinary care plan and service of meals at appropriate temperatures. N.J.A.C. 8:43D-8.4 would continue to establish that commercial food management firms must comply with the standards of this subchapter.

N.J.A.C. 8:43D-9

Subchapter 9 would continue to require the facility to ensure the provision of pharmaceutical services to residents, in accordance with physician orders and each resident's interdisciplinary care plan. Specifically, N.J.A.C. 8:43D-9.2 would continue to require the registered professional nurse to oversee the administration of prescribed or non-prescribed over-the-counter medication and document required findings. N.J.A.C. 8:43D-9.2 would also continue to permit the delegation of the administration of prescribed or non-prescribed over-the-counter medications to specially trained childcare workers. N.J.A.C. 8:43D-9.3 would continue to establish that a pharmacist or consultant pharmacist direct all pharmaceutical services, provide education for employees and residents, establish policies on the self-administration and storage of medication, review records quarterly and inspect areas utilized for storage or administration or disposal of medication. N.J.A.C. 8:43D-9.4 would continue to set forth the storage policies and practices for prescription and over-the-counter medication and the labeling and distribution of such medication.

N.J.A.C. 8:43D-10

Subchapter 10 would establish the requirement that facilities must ensure that social work services for residents will be provided by licensed or certified social workers, in accordance with New Jersey State Board of Social Work Examiners requirements.

N.J.A.C. 8:43D-11

N.J.A.C. 8:43D-11.1 would continue to require the availability of emergency medical services as well as a written plan for emergency transportation. N.J.A.C. 8:43D-11.2 would continue to set forth the requirement for the facility to develop written emergency plans, policies and procedures for medical emergencies, power failures, fire or natural disasters and file the plans with the Department. N.J.A.C. 8:43D-11.2 would continue to require the establishment of emergency procedures, which detail notification methods, use of emergency equipment, frequency of fire drills, diagram of evacuation routes and the training of personnel to appropriately react to these emergency situations. N.J.A.C. 8:43D-11.3 would continue to require the facility to conduct a monthly drill of its emergency plan, maintain documentation of drills, conduct at least one joint drill with the local fire department annually and inspect and maintain their fire extinguishers for use.

N.J.A.C. 8:43D-12

Subchapter 12 would continue to set forth the facility's responsibilities with respect to resident records. N.J.A.C. 8:43D-12.1 would continue to require the facility to retain in resident records a completed admission application, interdisciplinary care plan, all health care assessments and treatments, patient notes and personal information. N.J.A.C. 8:43D-12.2 would continue to establish that the records and information of an individual resident are confidential and may only be released if properly authorized. N.J.A.C. 8:43D-12.3 would continue to establish a 10-year record retention period for all resident records after resident discharge or until the resident's 20th birthday, whichever is longer. N.J.A.C. 8:43D-12.4 would continue to articulate that the records required to be kept by the subchapter shall be available on the premises for Department review at any time. N.J.A.C. 8:43D-12.5 would continue to require the facility to maintain and safeguard a current census register of all residents. N.J.A.C. 8:43D-12.6 would continue to require the administrator to provide written documentation confirming the pronouncement of resident death, disposition of the body and a record of notification to the family.

N.J.A.C. 8:43D-13

Subchapter 13 would continue to set forth resident rights. Among its principles are fostering independence and individuality, respect for each resident's privacy, encouraging family participation and providing an environment free from physical or sexual harassment and abuse, as well as corporal punishment.

N.J.A.C. 8:43D-14

N.J.A.C. 8:43D-14.1 would continue to govern housekeeping, sanitation, safety and maintenance, requiring all facilities to provide and maintain a sanitary and safe environment for residents. N.J.A.C. 8:43D-14.2 would continue to establish a standard for the development of a written work plan for housekeeping operations, including scheduling of all housekeeping operations and training programs for all housekeeping employees. N.J.A.C. 8:43D-14.3 would continue to list housekeeping and sanitation conditions that facilities must meet. N.J.A.C. 8:43D-14.3 would continue to require proper use of pesticides, household items and cleaning products and safe storage of combustible materials. N.J.A.C. 8:43D-14.4 would continue to set forth that facilities must collect, store and dispose all garbage in accordance with the rules of the New Jersey Department of Environmental Protection. N.J.A.C. 8:43D-14.5 would continue to establish heating and air conditioning requirements to ensure proper temperatures are maintained 24-hours a day. N.J.A.C. 8:43D-14.6 would continue to require the water supply to be operated and maintained in conformance with the New Jersey Safe Drinking Water Act. N.J.A.C. 8:43D-14.6 would also continue to require that hot water for bathing and handwashing be at least 95 degrees, but not exceed 110 degrees Fahrenheit. N.J.A.C. 8:43D-14.7 would continue to establish that the building and grounds be well maintained and kept free from fire hazards, as well as other residential health and safety hazards. N.J.A.C. 8:43D-14.8 would continue to establish the requirement that facilities develop and implement written policies and procedures for the facilities' laundry services.

N.J.A.C. 8:43D-15

Subchapter 15 would continue to govern infection prevention and control. N.J.A.C. 8:43D-15.1 would continue to require pediatric community transitional homes to employ a licensed professional nurse who, in coordination with the administrator, establishes a

policy and procedure manual, as well as an organizational plan for infection prevention and control. N.J.A.C. 8:43D-15.2 would continue to establish the minimum standards applicable to policies and procedures for surveillance, prevention and control of nosocomial infection and requires that they shall be consistent with the most recently published Centers for Disease Control and Prevention guidelines, the Hospital Infection Control Practices Advisory Committee recommendations and the practices of Occupational Safety and Health Administration. N.J.A.C. 8:43D-15.2 would continue to set forth the requirements that residents be immunized. N.J.A.C. 8:43D-15.3 would continue to establish the requirement for facilities to develop and implement general infection control policies and procedures and set forth minimum subject areas for which policies and procedures must be developed. N.J.A.C. 8:43D-15.4 would continue to establish tuberculosis screening procedures for employees in pediatric community transitional homes. N.J.A.C. 8:43D-15.4 would continue to require the development of disinfecting procedures and protocols, a rubella screening test and a rubeola (measles) screening test for employees under certain circumstances, the maintenance of employee and volunteer records on communicable disease, as well as the care of employees who become ill while at work or who have a work-related accident and for volunteers becoming ill or who have an accident while volunteering their time at the facility. N.J.A.C. 8:43D-15.5 would continue to require all staff members to be informed of the facility's infection control procedures, including personal hygiene requirements.

As the Department has provided a 60-day comment period on this notice of proposal, pursuant to N.J.A.C. 1:30-3.3(a)5, this notice is excepted from the rulemaking calendar requirement as set forth at N.J.A.C. 1:30-3.1 and 3.2.

Social Impact

The rules proposed for readoption have provided and would continue to provide appropriate minimum requirements for the provision of care at pediatric community transitional homes. The rules proposed for readoption have ensured and would continue to ensure effective pediatric community transitional home care and protection of resident health, safety and general welfare.

St. Clare's Home for Children in Neptune, the first pediatric community transitional home licensed in New Jersey, received its license on December 23, 2005. A second

pediatric community transitional home, AIDS Resource Foundation for Children in Elizabeth, was licensed on June 23, 2008. Several other potential pediatric community transitional homes in New Jersey are in the process of being licensed. Residents that have been and would be affected by the rules proposed for readoption and the proposed amendments and new rules are medically fragile children including, among others, children requiring care for HIV, AIDS, cerebral palsy, liver transplantation surgery aftercare, physical or emotional abuse problems or those who require GI tube feedings, intravenous infusion therapy, cardiac monitoring and/or respiratory therapy and monitoring. The Department expects the rules proposed for readoption with amendments and proposed new rules to have a favorable social impact on children in need of or residing at pediatric community transitional homes, as well as the surrounding community by providing minimum standards of acceptable care. For medically fragile children, pediatric community transitional homes are a more appropriate alternative to a prolonged stay in a higher level medical institution, since these homes are and would continue to be capable of providing health care, personal care and social services to children, from birth to 18 years of age, who require a lesser degree of medical care than that afforded them in an acute care hospital, as well as a transitional placement into mainstream community life. Licensure of these homes by the Department as health care facilities would add support to an existing foundation of necessary and positive services to improve the level and quality of care being provided to children in need.

The rules proposed for readoption would continue to promote high-quality supportive personal and health care services for medically fragile children in a community living environment. The rules proposed for readoption would continue to ensure the employment of qualified staff, a safe physical plant and environment, planned emergency services, adequate recordkeeping policies and procedures to oversee the provision of resident care and an interdisciplinary team approach to establishing a plan of care for each resident. The rules proposed for readoption would continue to enhance the quality of services for residents by establishing standards for functions, such as staffing, dietary, pharmacy, patient rights, employee health, infection control, housekeeping and maintenance. The accessibility and availability of these licensed services will help to

prevent fragmentation of services for medically fragile children and promote continuity of care.

The Department's proposed amendments to correct the name of the licensing unit and the health care facility inspection unit are technical and would have no social impact. The proposed amendments to set forth the required forms for licensure and request for waiver and the proposed new rules that would include the forms in chapter Appendices A and B would benefit pediatric community transitional homes by setting forth the methods by which they can obtain the forms, thereby fostering compliance with the process for licensure and waiver. The proposed amendments to prohibit smoking in pediatric community transitional homes would have the beneficial social impact of protecting the health of residents and staff at the homes and ensuring that the homes are in compliance with N.J.S.A. 26:3D-55 et seq., which prohibits smoking in health care facilities. The proposed amendments to the immunization requirement would have the beneficial social impact of removing outdated immunization recommendations and instead referencing up to date immunization recommendations and providing a reference to the existing immunization requirements at N.J.A.C. 8:57-4, applicable to residents that are entering into or attending schools, preschools or child-care centers. The proposed amendments to update the guidance on tuberculosis infection exposure and control and add an additional tuberculosis test, the interferon gamma release assay (IGRA), would have the beneficial social impact of providing additional ways to ensure continuity of quality infection control at pediatric community transitional homes.

Economic Impact

The Department foresees minimal financial impact to existing pediatric community transitional homes due to the rules proposed for readoption, since those homes in existence are already providing most, if not all services required by N.J.A.C. 8:43D. The Department anticipates that pediatric community transitional homes would only incur minimal costs, which will be readily absorbed. Since these homes already exist, no change in capital costs would result from the rules proposed for readoption and very little additional costs are expected to be associated with the implementation of policies and procedures that would be required to operate these homes. The pediatric community transitional homes would continue to be subject to a number of nonrefundable fee charges, such as a

charge of \$ 300.00 plus \$ 10.00 per bed for the filing of an application for licensure and annual renewal of the license, a biennial inspection fee of \$ 300.00, a relocation fee of \$ 250.00 and transfer of ownership fee of \$ 500.00. Pediatric community transitional homes would continue to have the same costs as they have always had since the promulgation of rules at N.J.A.C. 8:43D with regard to administrative responsibilities, such as reporting and recordkeeping; providing qualified staffing for the homes; ensuring the safety and sanitation of the physical plant and environment; and providing services for residents, including pharmaceutical, dining, transportation and social services. The Department does not anticipate any economic impact on the residents of pediatric community transitional homes due to the rules proposed for readoption or the proposed amendments and new rules.

No additional cost to the State or the public is expected to result from the licensing and inspection of these facilities. The Department will have sufficient resources to conduct surveys, respond to complaints and to continue to develop and maintain the rules at N.J.A.C. 8:43D. The delivery of services by licensed pediatric community transitional homes is expected to result in considerable economic savings when compared with the more costly institutional alternatives.

The Department's proposed amendment to add an additional tuberculosis test, the interferon gamma release assay, may have an economic impact by providing pediatric community transitional homes with an option for tuberculosis testing. By having an option, pediatric community transitional homes may be able to reduce the number of medical evaluations they complete and reduce two-step testing, which could result in cost savings. The Department's proposed amendments and new rules discussed in the Summary above would not have an economic impact.

Federal Standards Statement

The Department proposes the readoption of N.J.A.C. 8:43D with amendments and proposed new rules under the authority of N.J.S.A. 26:2H-1 et seq., particularly 26:2H-5, not under the authority of or in order to implement, comply with or participate in any program established under Federal law or standards or under a State statute that incorporates or refers to Federal law, standards or requirements. Therefore, a Federal standards analysis is not required.

Jobs Impact

The Department does not expect that any jobs will be generated or lost in the State of New Jersey as a result of the rules proposed for readoption with amendments and the proposed new rules.

Agriculture Impact Statement

The rules proposed for readoption with amendments and the proposed new rules would have no impact on the agriculture industry of the State of New Jersey.

Regulatory Flexibility Analysis

All existing pediatric community transitional homes are considered small businesses, as that term is defined in the Regulatory Flexibility Act, N.J.S.A. 52:14B-16 et seq. As described in the Summary above, the rules proposed for readoption and the proposed amendments and new rules would impose recordkeeping, reporting and other compliance requirements on pediatric community transitional homes. The costs to small businesses to comply with the rules proposed for readoption and the proposed amendments would be the same as the costs imposed on businesses generally, and are the same as those described in the Economic Impact above. A pediatric community transitional home may seek waiver of certain licensing requirements but, in doing so, the application must provide a satisfactory alternative proposal to ensure the protection of residents' health and safety needs. The proposed amendments and new rules would not require the pediatric community transitional homes to retain any professional services. The rules proposed for readoption would continue to require the pediatric community transitional homes to retain professional services because of the scope of their responsibilities as health care facilities caring for medically fragile children. For example, pediatric community transitional homes are required to retain a medical director who is licensed by the New Jersey State Board of Medical Examiners, a dietician or dietician consultant to complete the required dietary consultations, a registered professional nurse to assess the nursing needs of each resident, a pharmacist or pharmacist consultant to direct pharmaceutical services at the facility and social workers as needed for residents who require their services.

Pediatric community transitional homes would be responsible for meeting the Department's minimum standards at N.J.A.C. 8:43D and providing high-quality supportive

personal and health care services for medically fragile children whether their facilities are considered large or small businesses. The requirements set forth in the rules proposed for readoption and the proposed amendments are necessary to protect the health, safety and welfare of residents at pediatric community transitional homes. Therefore, the Department has determined that no differentiation based on business size is warranted.

Smart Growth Impact

The rules proposed for readoption with amendments and the proposed new rules would not have an impact on the achievement of smart growth and the implementation of the State Development and Redevelopment Plan.

Housing Affordability Impact

The rules proposed for readoption with amendments and the proposed new rules would have an insignificant impact on affordable housing in New Jersey and there is an extreme unlikelihood that the rules would evoke a change in the average costs associated with housing because the rules concern licensure standards for pediatric community transitional homes.

Smart Growth Development Impact

The rules proposed for readoption with amendments and the proposed new rules would have an insignificant impact on smart growth and there is an extreme unlikelihood that the rules would evoke a change in housing production in Planning Areas 1 or 2 or within designated centers under the State Development and Redevelopment Plan in New Jersey because the rules concern licensure standards for pediatric community transitional homes.

Full text of the rules proposed for readoption may be found in the New Jersey Administrative Code at N.J.A.C. 8:43D.

Full text of the proposed amendments and new rules follows (additions indicated in boldface **thus**; deletions indicated in brackets [thus]):

SUBCHAPTER 1. DEFINITIONS AND QUALIFICATIONS

8:43D-1.3 Definitions

The following words and terms, when used in this chapter, shall have the following meanings, unless the context clearly indicates otherwise:

...

"Application for New or Amended Acute Care Facility License (CN-7)" is the form, incorporated herein by reference and set forth at Appendix A, which a pediatric community transitional care home must complete and submit to the Department's Office of Certificate of Need and Healthcare Facility Licensure in order to apply for a license prior to commencement of new or expanded services and which is available through the following methods:

1. A written request to the Office of Certificate of Need and Healthcare Facility Licensure;

2. Electronically at the Department's Division of Health Facilities Evaluation and Licensing webpage at: <http://nj.gov/health/healthfacilities/forms.shtml>; and

3. Electronically at the Department's "Forms" webpage at:
<http://web.doh.state.nj.us/apps2/forms/>.

"Application for Waiver (CN-28)" is the form, incorporated herein by reference and set forth at Appendix B, which a facility must complete and submit to the Department in order to request a waiver of the rules established at N.J.A.C. 8:43D and which is available through the following methods:

1. A written request to the Office of Certificate of Need and Healthcare Facility Licensure;

2. Electronically at the Department's Division of Health Facilities Evaluation and Licensing webpage at: <http://nj.gov/health/healthfacilities/forms.shtml>; and

3. Electronically at the Department's "Forms" webpage at:
<http://web.doh.state.nj.us/apps2/forms/>.

. . .

"Commissioner" means the New Jersey State Commissioner of the Department of Health and Senior Services or his or her designee.

. . .

"Office of Certificate of Need and Healthcare Facility Licensure" means the health care facility licensing unit within the Division of Health Facilities Evaluation and Licensing of the Senior Services and Health Systems Branch of the Department.

1. The contact information is as follows:

i. Mailing Address: Office of Certificate of Need and Healthcare Facility Licensure, Division of Health Facilities Evaluation and Licensing, Department of Health and Senior Services, PO Box 358, Trenton, NJ 08625-0358; and

ii. Telephone number: (609) 292-5960.

"Office of Health Facilities Assessment and Survey" means the survey and inspections unit for acute care services within the Division of Health Facilities Evaluation and Licensing of the Senior Services and Health Systems Branch of the Department.

1. The contact information is as follows:

i. Mailing address: Office of Health Facilities Assessment and Survey, Division of Health Facilities Evaluation and Licensing, Department of Health and Senior Services, PO Box 367, Trenton, NJ 08625-0367; and

ii. Telephone number: (609) 292-9900.

. . .

SUBCHAPTER 2. LICENSURE PROCEDURES

8:43D-2.1 Application for licensure

(a) The Department shall charge a nonrefundable fee of \$ 300.00 plus \$ 10.00 per bed for the filing of an application for licensure of a pediatric community transitional care home and for the annual renewal of the license. [The facility shall receive a license for the maximum number of beds approved by the Department. Licensure forms may be obtained from:

Director

Certificate of Need and Acute Care Licensure

New Jersey Department of Health and Senior Services

PO Box 360, Room 403

Trenton, New Jersey 08625

609-292-5960]

1. Prior to commencement of new or expanded services, a pediatric community transitional care home shall complete and submit to the Department an

Application for New or Amended Acute Care Facility License (CN-7), as set forth at Appendix A.

i. The facility shall receive a license for the maximum number of beds approved by the Department.

2. The Department shall mail each licensed facility a License Renewal Form on an annual basis with instructions for completion and submission.

(b)-(c) (No change.)

(d) Each applicant for a license to operate a facility may make an appointment for a preliminary conference at the Department's **Office of Certificate of Need and [Acute Care] Healthcare Facility Licensure [Program]** to review all licensing requirements.

(e)-(j) (No change.)

8:43D-2.3 Surveys

(a) When the written application for licensure is approved and the building is ready for occupancy, a survey of the facility by representatives of the [Inspections, Compliance and Complaints Program of the Department] **Department's Office of Health Facilities Assessment and Survey** shall be conducted to determine if the facility adheres to the rules in this chapter.

1. (No change.)

2. The facility shall notify the [Inspections, Compliance and Complaints Program of the Department] **Department's Office of Health Facilities Assessment and Survey** when the deficiencies, if any, have been corrected, and the [Inspections, Compliance and Complaints Program] **Office of Health Facilities Assessment and Survey** shall schedule one or more resurveys of the facility prior to occupancy and licensure.

(b) (No change.)

8:43D-2.4 License

(a) A license shall be issued for a period of one year or less to a facility when the following conditions are met:

1.-8. (No change.)

9. If requested by the potential licensed operator, a preliminary conference for review of the conditions for licensure and operation (see N.J.A.C. 8:43D-2.1(e)1 through 7) has taken place between the **Department's Office of Certificate of Need and [Acute Care] Healthcare Facility Licensure [Program]** and representatives of the facility, who will be advised that the purpose of the conference is to allow the Department to determine the facility's compliance with N.J.S.A. 26:2H-1 et seq., as amended, and the rules pursuant thereto.

(b) No facility shall admit residents to the facility until the facility has the written approval and/or license issued by the **Department's Office of Certificate of Need and [Acute Care] Healthcare Facility Licensure [Program of the Department]**. Violators of this requirement will be subject to penalties for operating a facility without a license, pursuant to N.J.S.A. 26:2H-14 and N.J.A.C. 8:43E.

(c)-(g) (No change.)

8:43D-2.5 Surrender of license

The facility shall notify each resident, the resident's primary care provider, and any guarantors of payment at least 30 days prior to the voluntary surrender of a license, or as directed under an order of revocation, refusal to renew, or suspension of license. In such cases, the license shall be returned to the **Department's Office of Certificate of Need and [Acute Care] Healthcare Facility Licensure [Program of the Department]** within seven working days after the voluntary surrender, revocation, non-renewal[,], or suspension of the license.

8:43D-2.6 Waiver

(a) (No change.)

(b) A facility seeking a waiver of these rules shall apply in writing [on a form provided by] **to** the Department [to the Director of the Certificate of Need and Acute Care Licensure Program of the Department] **using the Application for Waiver (CN-28), as set forth at Appendix B.**

[(c) A written request for waiver shall include the following:

1. The specific rule(s) or portion(s) of the rule(s) for which waiver is requested;

2. The reasons for requesting a waiver, including a statement of the type and degree of hardship that would result to the facility if the waiver does not issue;
 3. An alternative proposal which would ensure resident safety and meet the overall intent of these rules; and
 4. Documentation to support the request for waiver.]
- [(d)] **(c)** (No change in text.)

SUBCHAPTER 4. GENERAL REQUIREMENTS

8:43D-4.2 Ownership

(a) The ownership of the facility, as well as the property on which it is located, shall be disclosed to the Department. Any proposed change in ownership shall be reported to the Director of the **Department's Office of** Certificate of Need and [Acute Care] **Healthcare Facility** Licensure [Program of the Department], in writing and in conformity with N.J.A.C. 8:43D-2.4(d)2.

(b)-(d) (No change.)

8:43D-4.3 Submission and availability of documents

The facility shall, upon request, submit any documents, which are required by the rules set forth in this chapter, to the Director of the **Department's Office of** Certificate of Need and [Acute Care Licensing Program of the Department] **Healthcare Facility Licensure**. Additionally, upon request by the Department, the facility shall submit, in writing, data related to utilization, demographics, costs, charges, staffing[,], and other planning and financial data necessary for the Department to evaluate the facility.

8:43D-4.7 Reportable events and notification requirements

(a) The facility shall notify the Department [immediately] **within three hours** by telephone at (609) 292-9900 or (800) 792-9770 (after business hours), followed within 72 hours by written confirmation to the Department's **Office of** Certificate of Need and [Acute Care] **Healthcare Facility** Licensure [Program], of the following:

1.-3. (No change.)

(b)-(c) (No change.)

8:43D-6.1 Resident care policies and procedures

(a) There shall be a resident care policy and procedure committee that shall consist of at least the administrator, director of nursing and the medical director, which shall establish written resident care policies and procedures, which shall be reviewed at least every three years. Each review of the policies and procedures shall be documented. Policies and procedures shall include, but not be limited to, those relating to:

1.-5. (No change.)

6. The [control] **prohibition** of smoking in the facility in accordance with N.J.S.A. 26:3D-[1]**55** et seq.;

[i. At the facility's option, a smoke-free policy may be implemented, which shall include adequate notice to all resident applicants prior to admission to the facility;

ii. A facility which permits smoking shall have designated smoking areas with adequate outside ventilation, in accordance with (a)6iv below;

iii. Nonflammable ashtrays in sufficient numbers shall be provided in designated smoking areas;

iv. Any room designated for smoking shall meet the following ventilation requirements for acceptable indoor air quality:

(1) A ventilation system which prevents contaminated air from recirculating through the facility;

(2) The number of air changes per hour within the designated smoking room shall be equivalent to the number necessary to achieve 60 cubic feet per minute per smoker, based on occupancy of no greater than five smokers per 100 square feet; and

(3) Negatively pressurized air to prevent backstreaming of smoke into nonsmoking areas of the facility;]

7.-11. (No change.)

SUBCHAPTER 14. HOUSEKEEPING, SANITATION, SAFETY AND MAINTENANCE

8:43D-14.3 Resident environment

(a) (No change.)

(b) The following safety conditions shall be met:

1.-6. (No change.)

7. If pets are allowed in the facility, the facility shall provide safeguards to prevent interference in the lives of residents. Guidelines for pet-facilitated therapy may be requested from the Department's **Office of** Certificate of Need and [Acute Care] **Healthcare Facility** Licensure [Program]; and

8. (No change.)

SUBCHAPTER 15. INFECTION PREVENTION AND CONTROL SERVICES

8:43D-15.2 Development of infection control policies and procedures

(a)-(b) (No change.)

(c) [Residents shall be] **The facility shall ensure that residents are** immunized in accordance with ["Recommended Childhood Immunization Schedule, United States, January--December 2000" as approved by the Advisory Committee on Immunization Practices (ACIP), the American Academy of Pediatrics (AAP), and the American Academy of Family Physicians (AAFP). The ACIP guidelines listed above are available by writing to ACIP, U.S. Public Health Service, Centers for Disease Control and Prevention, Atlanta, Georgia 30333. The AAP guidelines are available by contacting AAP, P.O. Box 927, Northwest Point Blvd., Elk Grove, Illinois 60009-0927. The AAFP guidelines may be obtained by contacting the AAFP, 11400 Tomahawk Creek Parkway, Leawood, Kansas 66211-2672] **the 2008 Recommended Childhood and Adolescent Immunization Schedules approved by the Advisory Committee on Immunization Practices, the American Academy of Pediatrics, and the American Academy of Family Physicians, which is amended yearly, and which is available through written request mailed to the New Jersey Vaccine Preventable Disease Program, Department of Health and Senior Services, PO Box 369, Trenton, NJ 08625-0369, or online at** <http://www.cdc.gov/vaccines/recs/schedules/default.htm#child>.

1. Residents entering into or attending a school, preschool or child-care center shall comply with the immunization requirements set forth at N.J.A.C. 8:57-4, Immunization of Pupils in School.

8:43D-15.4 Employee health and resident policies and procedures for infection prevention and control

(a) Tuberculosis screening: The facility shall establish policies and procedures for the detection and control of the transmission of *M. tuberculosis* that includes, but is not limited to, developing a [tuberculosis] **Tuberculosis Infection** Exposure Control Plan (["TB plan"]), according to the guidelines set forth in "Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-Care [Facilities] **Settings**, [1994] **2005**." MMWR. [October 28, 1994] **December 30, 2005**, volume [43] **54**, Number RR-[13]**17**, p. [1-132] **1-141**, pursuant to the Occupational Safety and Health Act (OSH Act) of 1970, incorporated herein by reference as supplemented and amended.

1. Newly hired employees: The facility shall identify a new employee's baseline status of exposure to *M. tuberculosis*. The facility shall **either draw blood for an interferon gamma release assay (IGRA) or** administer a two-step Mantoux tuberculin skin test, using five tuberculin units of purified protein derivative, upon the employment of full- and part-time employees, volunteer staff[,] and primary care providers, either salaried by the facility or with clinical privileges to provide medical care at the facility.

i. **Employees with an IGRA result of "positive" have latent TB infection, a "negative" result indicates no latent TB infection and employees with an "indeterminate" result shall repeat the IGRA.**

[i.] ii. Employees with [a] **an initial Mantoux skin test result of "negative"** (<10 mm of induration or < five mm of induration if the individual is immunosuppressed) [result following the first Mantoux skin test are] **shall be** administered a second test in one to three weeks.

[ii.] iii. Employees with **either a "positive" IGRA or a "positive"** ([>]>=10 mm of induration or [>]>=five mm of induration if the individual is immunosuppressed) **Mantoux skin test** result following either the first or second test are referred for a medical evaluation to determine whether there is evidence of latent tuberculosis infection or active tuberculosis disease.

(1) (No change.)

(2) The facility shall permit employees with positive **IGRA or** Mantoux test results to begin working after [the employee has] **they have** submitted **a** written medical clearance to the facility.

2. Exceptions to the requirements in (a)1 above are as follows:

i. (No change.)

ii. Employees who provide documentation of positive **IGRA or** Mantoux skin test results shall be exempt from screening.

iii. (No change.)

3. Periodic screening of personnel: The facility shall establish policies and procedures for the periodic screening of *M. tuberculosis* in eligible personnel, including, but not limited to, **the following testing standards**:

i. [Testing:] The facility shall administer [a] **an IGRA or** Mantoux skin test to all **IGRA or** tuberculin-negative employees annually at **a** minimum. Frequency of testing shall be determined by the level of risk assigned by the facility's TB plan[; and].

(1) Medical evaluation, as described in (a)1iii(1) above, is required of any employee with a previously negative test result that, upon follow-up testing, is positive to either the IGRA or Mantoux test.

(2) An asymptomatic employee referred to medical evaluation may continue to work until he or she submits a written medical clearance, but a symptomatic employee cannot return to work until he or she submits a written medical clearance.

[ii.Recordkeeping:]

[(1)] **4.** The facility shall maintain records of employee **IGRA or** Mantoux test results.

[(2) The facility shall submit the results of employee Mantoux tuberculin testing bi-annually to the New Jersey Department of Health and Senior Services, on forms provided by the Department, at the address listed below.]

(b)-(l) (No change.)

(m) The facility shall maintain records documenting [contagious] **communicable** diseases contracted by employees during employment **or residents during their stay in**

the facility and complete required reporting, as specified at N.J.A.C. 8:57-1.3(a) and (b), **2 or 5, as applicable.**

(n) (No change.)

(Agency Note: The text of proposed new N.J.A.C. 8:43D Appendices A and B follows without boldface symbolizing proposed new text; those portions of the appendices appearing in boldface are proposed to be so permanently.)

APPENDIX A

The "Application for New or Amended Acute Care Facility License," CN-7, is available on the Internet at <http://www.state.nj.us/health/forms/cn-7.pdf>.

APPENDIX B

The "Procedure for Submission of a Waiver Request," CN-28, is available on the Internet at <http://www.state.nj.us/health/forms/cn-28.pdf>.